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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/177,711 10/23/98 ADAMS

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EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application N .

09/177,711

Applicant(s)

ADAMS ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on March 7, 2000 & June 23, 2000 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-40, 45-51 and 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-40, 45-51 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____ .
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 20) ☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Invention Group II, claims 35-40 and 45-51 in Paper No. 9 submitted March 7, 2000 is acknowledged. Applicant's election without traverse of species glyceryl trinitrate in Paper No. 11 submitted Jun 23 is also acknowledged.
2. The claims have been examined insofar as they read on the elected species.

Claim Rejections 35 U.S.C. – 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 35-40, 45-51 and 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Anfossi et al. (Gen. Pharmac. Vol. 25, No. 6, p 1093-1100) and Maurice et al. (IDS-AY) in view of Synder et al. (US patent 5,439,938, IDS-AB), Gozes et al. (US Patent, 5,217,953) and Stamler et al. (US Patent, 5,380,758)
5. Both Anfossi et al. and Maurice et al. teach a method to augment the effect of cAMP as well as augment the effect of cGMP by using one or more agents. See, the abstract in Anfossi et al. and pages 677-679 in Maurice et al. One of the agent is nitrovasodilator, i.e., a nitric oxide generator. See, particularly, page 677, right-hand column, the last paragraph in Maurice et al.. The nitrovasodilator can be glyceryl trinitrate. See, particularly, the abstract in Anfossi. The nitrovasodilator increase the level of cGMP as well as the level of cAMP by inhibition of cAMP breakdown. The inhibition of cAMP breakdown is suggested to be due to nitric oxide's inhibitory activity to cyclic nucleotide phosphodiesterase. See, particularly, page 678, right-hand

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column and page 679, left-hand column in Maurice. A synergistic effect would be produced when nitrovasodilator is combined with an agent which directly activates adenylyl cyclase such as forskolin. See, particularly, the abstract in Anfossi et al. and page 677, right-hand column in Maurice et al.

The primary references do not teach expressly to employ the said method for treatment for erectile dysfunctions.

However, Stamler et al teach that agent augmenting the effect of cGMP is known to be useful for treating erectile dysfunctions. See, particularly, the abstract and column 10, line 63 bridging column 11, line 14. Gozes et al. teach that agents augmenting cAMP, e.g., VIP is known to be useful for treating erectile dysfunction. See, particularly, column 1, lines 33-54. More particularly, Snyder discloses that glyceryl trinitrate is known to be useful for treating erectile dysfunction. See, particularly, column 2, lines 23-27 and claim 29.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to modify the method taught in the primary references for treating erectile dysfunctions by administering the active agent to a subject..

A person of ordinary skill in the art would have been motivated to modify the method taught in the primary references for treating erectile dysfunctions because agents augmenting the effect of cAMP and/or cGMP are known to be useful for treating erectile dysfunctions and the particularly agents, e.g., VIP and glyceryl trinitrate are known to be useful for treating erectile dysfunction. Optimization of the method of administration of the active agent is considered within the skill of artisan, absent evidence to the contrary. Further, since the steps of the fairly suggested method is substantially identical with the claimed method, i.e., administering the

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active agents to a subject, it would have been reasonably expected that the agents would function through a same mechanism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

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July 27, 2000


MINNA MOEZIE
PRIMARY EXAMINER